Remarks/Arguments:

This is a reply to the office action of January 19.

Independent claims 72 and 105 have been amended; claims 143 - 164 are new. The claims now presented better distinguish the invention from the prior art, particularly Shonk's patent 5304135.

Claim 72 as amended recites limitations including:

(A) the wall cavity extending without interruptions and/or openings, longitudinally relative to the balloon structure, between the distal end and at least a portion of the proximal shank ,

(B) the wall cavity following the balloon structure outline from the distal end to at least a portion of the proximal shank ,

(C) said wall cavity, suitable for housing a guide wire, defines a guide wire lumen between the distal end and at least a portion of the proximal shank ,

(D) the wall cavity has an opening which forms a guide wire lateral opening to allow a guide wire to be inserted in the wall cavity or to emerge therefrom.

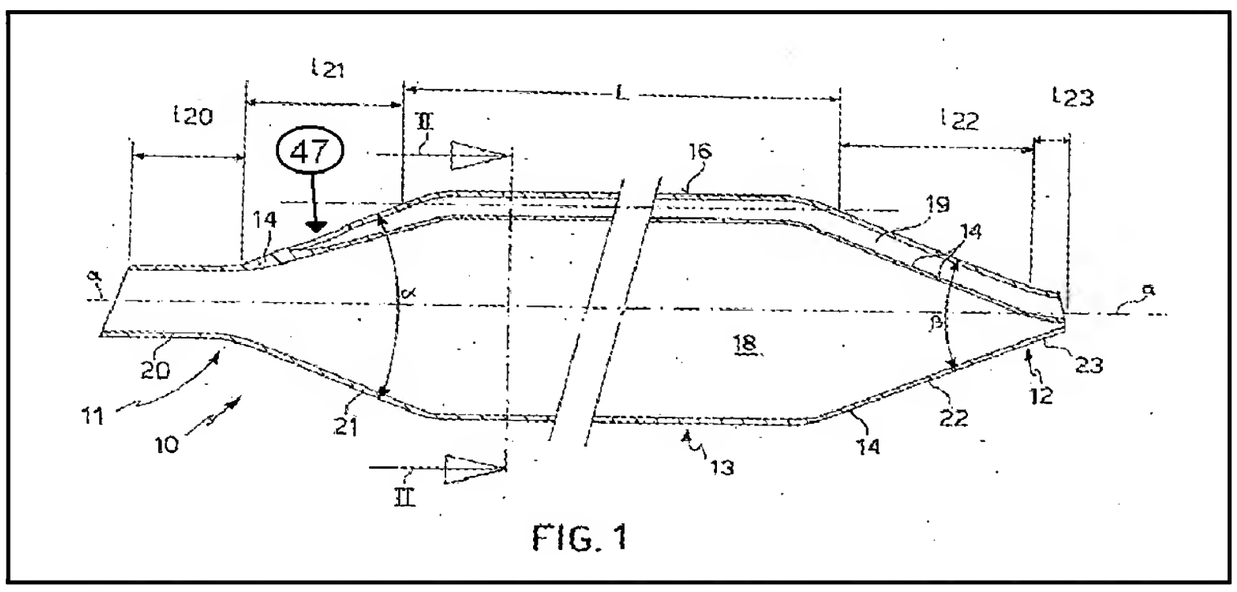


FIG. 1

These limitations are supported by the original application:

Feature "A" is supported by Fig. 1, which represents the wall cavity 19 that extends from the distal end 23 until the proximal shank (see point near 14).

The Examiner rejected claims 72 - 101, 105, 113 and 114 under 35 USC 112 on the ground that feature "B" "is considered new subject matter... as seen in Fig.1 where the slope in the proximal portion is different".

Note that "to follow the outline" does not necessarily mean having the same slope. What is meant is that the wall cavity 19 delimits the inflation chamber 18 and follows the outline of the balloon from the distal end until at least a portion of the proximal shank, as represented in Fig 1 and Fig 25.

Feature "C" is fully supported by description, for example:

[0070] ... *the sliding of a guide wire housed in the wall cavity 19*;

[0072] ... *one or more guide-wire cavities 19 and 34.*

Feature "D" is supported by Fig 1 and Fig 25 and also by description:

[0106] ...*the wall portion which separates the wall cavity from the outer surface has an opening which forms a lateral aperture 47 to allow a guide wire to be inserted in the wall cavity 19 or to emerge therefrom.*

Claim 143

New claim 143 recites a combination including:

(E) the wall cavity extending without interruptions and/or openings, longitudinally relative to the balloon structure, between the distal end at least the proximal shank,

(F) the wall cavity following the balloon structure outline from distal end to at least the proximal shank,

(G) said wall cavity, suitable for housing a guide wire, defines a guide wire lumen between the distal end at least the proximal shank

(H) a proximal aperture of the wall cavity is produced a predetermined distance from the proximal shank, in the direction proximal from the balloon,

(I) said aperture forms a guide wire opening to allow a guide wire to be inserted in the wall cavity or to emerge therefrom.

These limitations are supported by the original patent application.

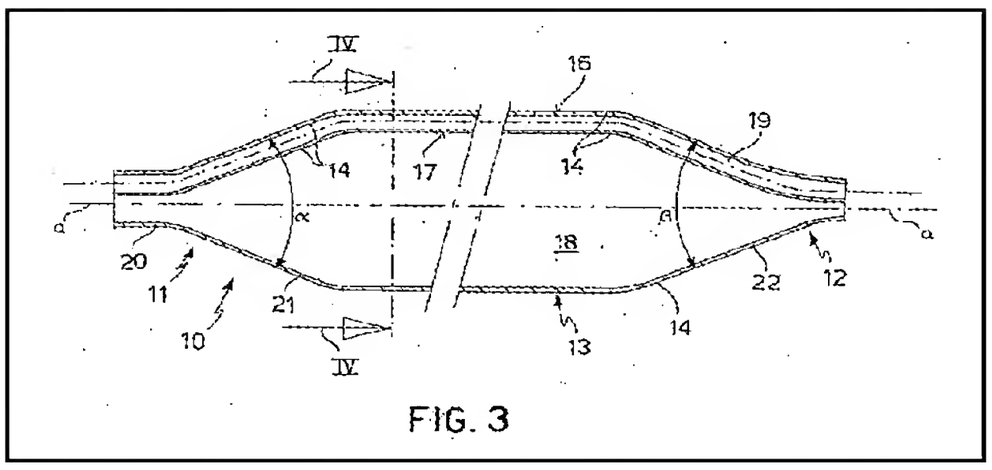


FIG. 3

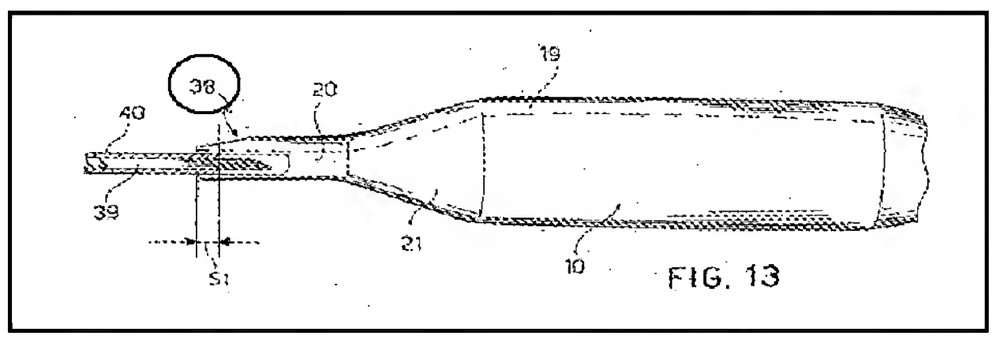


FIG. 13

Feature "E" is supported by Fig. 3, which shows the wall cavity 19 that extends between the distal end 12 and the proximal shank (see point near 20).

Regarding feature "E", the Examiner stated that "is considered new subject matter… as seen in Fig.1 where the slope in the proximal portion is different". We note again that "to follow the outline" does not necessarily mean having the same slope. Nevertheless, in this configuration the wall cavity also does have same slope. What is intended is that the wall cavity 19 delimits the inflation chamber 18 and follows the outline of the balloon from the distal end until at least the proximal shank, as illustrated in Figs 3 and 13.

Feature "G" is fully supported by description, for example:

[0070] … *the sliding of a guide wire housed in the wall cavity 19*;

[0072] … *one or more guide-wire cavities 19 and 34.*

Feature "H" is supported by Fig 3, Fig 13, and description [0106]. In particular, the wall portion which separates the wall cavity 19 from the outer surface has an opening which forms a lateral aperture 38 to allow a guide wire to be inserted in the wall cavity 19 or to emerge therefrom. Moreover, "*a proximal aperture of the wall cavity 19 is produced a predetermined distance from the balloon or, for example, from the proximal shank 21, in the direction away from the balloon*" [0085].

Claim 154

New claim 154 recites a combination of features including:

(J) said wall cavity is suitable for housing a guide wire and represents a portion of a guide wire lumen that extends in a proximal direction beyond the balloon structure proximal end.

These limitations are described in the original patent application.

- at least one wall cavity is provided in the wall between the outer surface and the inner surface, the wall cavity extending without interruptions and/or openings, longitudinally relative to the balloon structure, between the proximal and the distal end, the wall cavity following the balloon structure outline from the proximal end to the distal end

This feature is supported by Fig. 3 and Fig 16, which show the wall cavity 19 that extends between the proximal end 20 and the distal end 12.

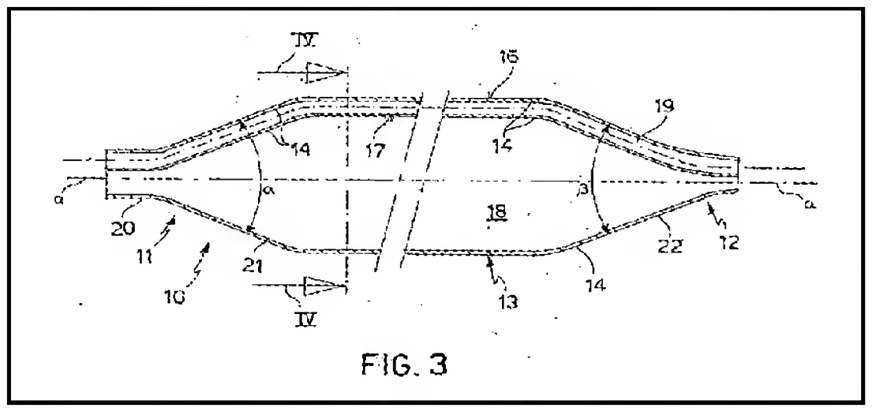


FIG. 3

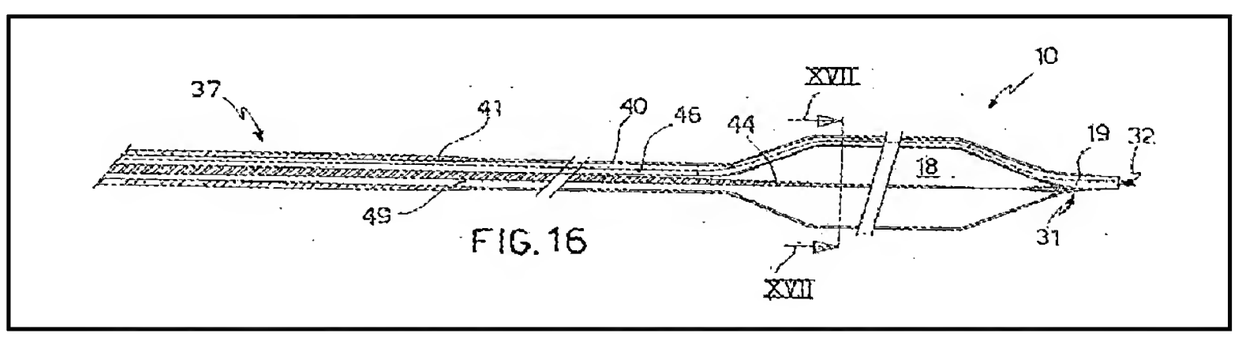


FIG. 16

Moreover, "*the wall cavity 19 is within the wall 14 which delimits the inflation chamber 19 for the whole of its extent that affects the balloon structure*" [0057]; therefore, the wall cavity 19 follows the outline of the whole balloon.

- *said wall cavity is suitable for housing a guide wire*

This feature is fully supported by description:

[0070] ... *the sliding of a guide wire housed in the wall cavity 19*;

[0072] ... *one or more guide-wire cavities 19 and 34*;

- *and represents a portion of a guide wire lumen that extends in a proximal direction beyond the balloon structure proximal end.*

This feature is fully supported by Fig 16 and by the description:

[0108] ...*balloon structure 10 connected proximally to a shaft 37 comprising a guide-wire cavity 46 that is connected to the wall cavity 19 in a leaktight manner for the passage of a guide wire*" .

We respectfully submit that the limitations of the claims now presented are fully supported by the specification.

NOVELTY

The claims under consideration were rejected as anticipated by or obvious over Shonk.

Shonk discloses a multi-chamber balloon having a primary elongated inflatable balloon 12 defining a first chamber 20, and a secondary elongated inflatable balloon 22 defining a second chamber 30 [col 2, lines 19-28].

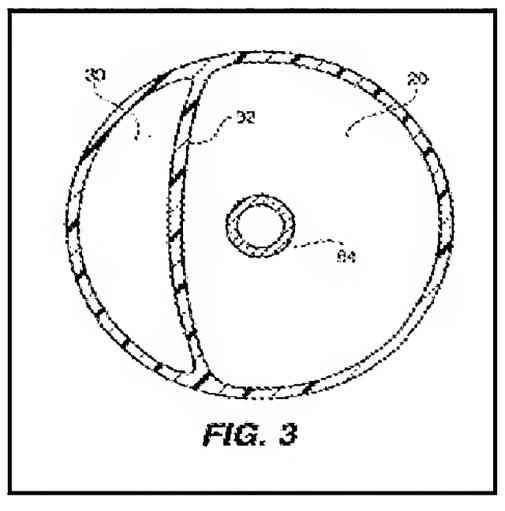


FIG. 3

The device described by Shonk has a first linear diameter-pressure curve defined by the primary balloon 12, a second

linear diameter-pressure curve defined by the secondary balloon 22, and a third linear diameter-pressure curve defined by the combination or addition of the primary and secondary balloons 12 and 22 [col 2, lines 33-43].

Shonk's device has a "wall cavity" 30 suitable to be inflated as a balloon: the balloons 12 and 22 have openings 17 and 27 for inflation thereof, respectively [col 2, lines 43-46]; the device 34 is designed to use primary balloon 12 to dilate a stricture first, and if not sufficient, the secondary balloon 22 is used to supplement the primary balloon 12 [col 2, lines 62-65].

Claim 72 requires that

said wall cavity, suitable for housing a guide wire, defines a guide wire lumen between the distal end and at least a portion of the proximal shank ,

the wall cavity has an opening which forms a guide wire lateral opening to allow a guide wire to be inserted in the wall cavity or to emerge therefrom.

Shonk describes neither (a) a wall cavity defining a guide wire lumen suitable for housing a guide wire, nor (b) an opening which forms a guide wire opening to allow a guide wire to be inserted into the wall cavity or to emerge therefrom. Therefore, claim 72 is novel over Shonk.

Claim 143 requires that:

said wall cavity, suitable for housing a guide wire, defines a guide wire lumen between the distal end at least the proximal shank

a proximal aperture of the wall cavity is produced a predetermined distance from the proximal shank, in the direction proximal from the balloon,

said aperture forms a guide wire opening to allow a guide wire to be inserted in the wall cavity or to emerge therefrom.

Shonk's wall cavity does not define a guide wire lumen, much less one having a proximal aperture into which a guide wire can be inserted.

Claim 154 requires that:

said wall cavity is suitable for housing a guide wire and represents a portion of a guide wire lumen that extends in a proximal direction beyond the balloon structure proximal end.

This claim is also novel over Shonk, which does not have a wall cavity which represents a portion of a guide wire lumen.

It is submitted that independent claims 72, 143 and 154 – and thus the dependent claims which refer to those claims – are novel over Shonk.

NON-OBVIOUSNESS

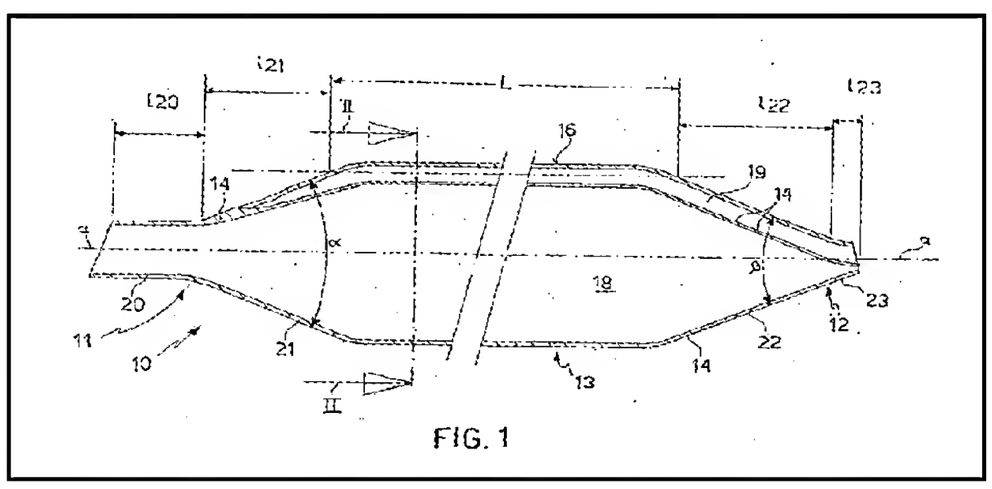


FIG. 1

The present invention is a balloon structure which allows a guide wire to pass through a distal guidewire aperture (near 12) and to slide through a guide-wire wall cavity 19 which, at least for its section corresponding to the extent of the balloon, is disposed in the balloon wall, and causing the wire to emerge from a proximal aperture, relative to the balloon [0116].

It can be appreciated that, owing to the balloon structure described above, there are no obstructions inside the inflation chamber 18, so that rapid inflation and deflation of the balloon are facilitated [0118].

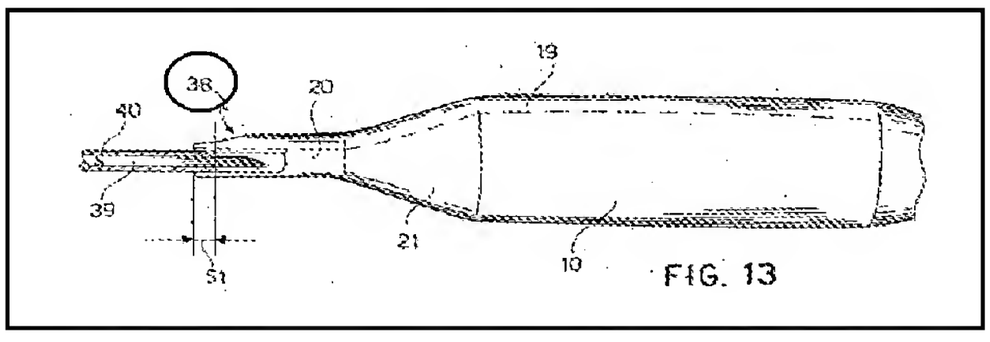


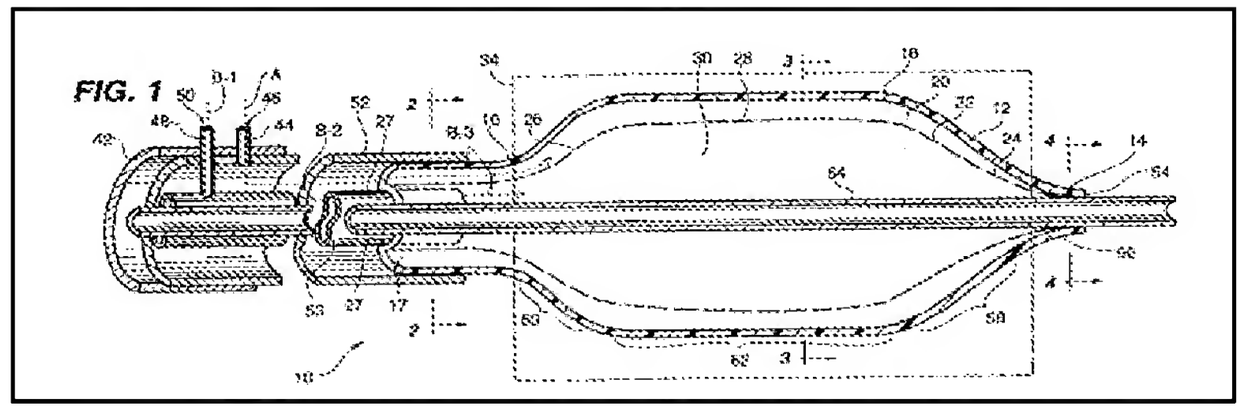
FIG. 13

Because the guidewire cavity 19 is provided in the wall of the balloon

structure – rather than through the balloon chamber – there are no obstructions inside the inflation chamber 18. Therefore, the admission of fluid to inflate or expand the balloon, as well as the discharge of the fluid to contract the balloon so as to reestablish flow of blood in the vessel, are particularly quick at constant overall dimensions of the catheter [0125].

A corollary is that, for a given performance with regard to balloon inflation and deflation speed, it is possible to produce catheters of very limited transverse dimensions which can reach even very small vessels [0119]

As can be seen in the figure to the right, Shonk discloses a balloon assembly 10 that includes a catheter 64. The catheter 64 is enclosed in the primary balloon 12 in alignment with an elongate axis for facilitating the insertion of the variable dilation device in a body cavity [col. 3, lines 38-42].



Thus Shonk describes a standard balloon catheter construction, in which the catheter (and in particular the guide wire lumen) is disposed within the inflation chamber 20 of the balloon, actually in the center of the balloon, in alignment with the longitudinal axis of the structure.

Compared to Shonk, the present invention permits more rapid inflation and deflation of the balloon, and consequently, allows one to reduce the inflation and deflation time. It is submitted that Shonk would not have led a person of ordinary skill in the field of this invention to the invention recited in the claims now presented.

We believe that this application is in condition for allowance.

Respectfully,

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